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(54) **FORMULATIONS FOR THE TREATMENT OF INSULIN RESISTANCE AND TYPE 2 DIABETES MELLITUS**

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(58) **Field of Search** 424/451, 464, 424/472, 482, 486, 489; 514/251

(56) **References Cited**

U.S. PATENT DOCUMENTS

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(57) **ABSTRACT**

The compositions and dosage forms of the invention are clinically useful as methods for increasing the effectiveness, efficiency and safety of biguanides (metformin) and/or sulfonylureas in the prevention and treatment of insulin resistance and diabetes mellitus, alone or in combination, as a nutrient for humans. The carefully chosen active ingredients of the invention are designed in a modular fashion to prevent and rectify adverse events associated with insulin resistance syndrome and diabetes mellitus, and with the clinical use of biguanides (metformin) and/or the sulfonylureas. These modules are: (1) Mitochondrial Metabolic Group, (2) Plasma and Mitochondrial Membrane Integrity Group, (3) Nocturnal Group and, (4) Insulin Alternative Group. When used in concert with a biguanide, a sulfonylurea or with a combination of both, the invention will broaden the clinical usefulness of these drugs. The invention will retard the progression of insulin resistance to type 2 diabetes, and reduce the serious microvascular and macrovascular complications commonly associated with insulin resistance syndrome and diabetes mellitus.

24 Claims, No Drawings